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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/190,138
Filing Date: November 12, 1998
Appellant(s): BOSCH ET AL.

Attorney Michele M. Simkin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 6, 2006 appealing from the Office action mailed January 14, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. The Examiner agrees with the Applicant's assertion that the appeal of 09/577,489 is unrelated to the instant application.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,985,309	Edwards	11-1999
5,202,110	Dalby	4-1993
5,145,684	Liversidge	9-1992
	Goodman & Gilman's, "The Pharmacological Basis of Therapeutics. Ninth edition," McGraw-Hill, 1996, page 666.	

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claims 11-34, 40, 41, 44, 45, 47, 48, 51-62, 69-96, and 111-119 are rejected under 35 U.S.C. § 103(a) over Edwards et al. U.S. Patent No. 5,985,309 ("Edwards" or "'309").

'309 teaches aerosol particle compositions that are less than 100 microns in diameter and have a surface modifier adsorbed thereon. The surface modifiers can be found at column 7, lines 55-63 and in the examples and are the same as those of the instant application as stated on page 26, line 10-page 27, line 28. '309 also discloses the spray-drying and freeze-drying the compositions. Example 14 discloses that the concentration of drug is within the instant ranges (i.e. 200 μg/5mg albuterol is equivalent to 40 mg/g). The compositions of the instant claims and those of '309 do not appear to be different. Both are aerosol compositions comprising spray- or freeze-dried drug particles less than about 100 μm, and deliver an agent to the deep lung (C 9, L 59-63). Furthermore, '309 teaches that varying the spray drying parameters, the aerodynamic properties of the inhaled particles can be effectively controlled through, for example, adjusting the inlet temperature or the feed rate and pressure of the compressed air to alter particle size (C 27, L 12-31) resulting in particle sizes that provide optimal deposition within targeted sites within the respiratory tract.

Below are the citations from the Edwards reference (USPN 5,985,309):

Surfactants known in the art can be used including any naturally occurring surfactant. Other exemplary surfactants include diphosphatidyl glycerol (DPPG); hexadecanol; fatty alcohols such as polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid, such as palmitic acid or oleic acid; sorbitan trioleate (Span 85); glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester such as sorbitan trioleate; tyloxapol and a phospholipid.

column 7, lines 55-63

have a diameter within the selected range. The presence of the higher proportion of the aerodynamically light, larger diameter (at least about 5 μm) particles in the particle sample enhances the delivery of therapeutic or diagnostic agents incorporated therein to the deep lung.

Column 9, lines 59-63

EXAMPLE 14

Release Properties of Albumin:DPPC:Lactose:Albuterol Particles

Particles (mean diameter 10 μm, tap density 0.06 gram/cm^3) were prepared particles as described in Example 7 with 60% DPPC, 18% albumin, 18% lactose, and 4% albuterol to demonstrate that sustained release of a hydrophilic molecule such as albuterol can also be achieved without cholesterol. The in vitro release of albuterol is shown in FIG. 7 both for this formulation and a non-sustained release formulation that included only lactose (96%) and albuterol (4%). Even without cholesterol, the release of the albuterol was sustained for nearly 24 hours.

Particles (5 mg, i.e. 200 μg albuterol dose) were administered to guinea pigs using the procedures in Example 12 to demonstrate that the sustained release albuterol particles could produce sustained bronchodilation. The animals were administered carbachol prior to measuring airway resistance. Airway resistance was monitored using a Buxco system. Airway resistance dropped sharply following inhalation of the large porous particles (FIGS. 7 and 8) and remained at statistically low levels for approximately 1 day (n=y).

"Placebo" particles (60% DPPC, 20% albumin, 20% lactose) prepared as described in Example 11 were also administered. Airway resistance following carbachol challenge was measured at eight hours following inhalation and 15 hours following inhalation. The airway resistance was

1.0±0.3 and 1.0±0.2 cm H_2O/ml/sec., proving that the bronchodilation observed in FIG. 8 was due to slow albuterol release.

Slow albuterol release has also been achieved in vitro using particles prepared by the methods of Example 7 with 10% DPPC, 86% albumin, and 4% albuterol. However particles prepared with 10% DPPC, 43% albumin, 43% lactose, and 4% albuterol did not display significantly slower albuterol release in vitro, indicating that for relatively low DPPC content, high albumin content is favorable for sustained albuterol release.

These examples demonstrate that by choosing the composition of the spray dried materials and by varying the spray drying parameters, the aerodynamic properties of the inhaled particles can be effectively controlled. More specifically, the composition of the spray dried material especially affects the density and shape of the particles while the spray drying parameters have a stronger affect on their size. For instance, increasing the proportion of lactose in the particles make the particles heavier, while increasing the albumin or dipalmitoyl phosphatidylcholine (DPPC) content makes them lighter. Increasing DPPC content also increases the particle size. Nevertheless, when a relatively small proportion of drug is incorporated in the particles, the characteristics of the particles remain relatively unaffected. Decreasing the inlet temperature largely increases the size of the particles without greatly affecting their tap density. Increasing the feed rate and decreasing the pressure of the compressed air both tend to increase the size of the particles without greatly affecting their density. However, these effects are smaller than those of the temperature.

Example 14 continued and col. 27, lines 12-31

(b) Claims 11-34, 40-45, 47, 48, 51-62, 65-96, and 97-119 are rejected under 35 U.S.C. § 103(a) over Edwards et al. U.S. Patent No. 5,985,309 in view of Liversidge U.S. Patent No. 5,145,684 ("Liversidge").

The '309 reference is relied upon for all that it teaches as stated above in part (a) of this section.

The '684 reference teaches particle compositions that are much less than 100 microns in diameter and have a surface modifier adsorbed thereon (e.g. abstract; col. 2, lines 38-43; and Example 2). The particles of '684 are for the administration of poorly soluble drugs (col. 3, lines 38-45), such as corticosteroids (e.g. col. 4, lines 15-20 and Examples 1-6) (known for the treatment of asthma and allergies by administration in metered dose inhalers) and are produced by milling under non-pressurized conditions, such as are taught in Example 2. After milling the particles are separated from the milling dispersion to yield particles that appear to be the same as those of the instant invention, absent a demonstration of criticality thereto.

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of '309 and '684 to provide aerosol corticosteroid particle formulations that meet the limitations of the instant claims based upon the treatment of asthma and allergies and that the rate of dissolution of a particulate drug can increase with increasing surface area, i.e. decreasing particle size, along with providing optimal deposition with targeted sites within the respiratory tract.

Below are relevant citations from the Liversidge reference (USPN 5,145,684):

[57] ABSTRACT

Dispersible particles consisting essentially of a crystalline drug substance having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 400 nm, methods for the preparation of such particles and dispersions containing the particles. Pharmaceutical compositions containing the particles exhibit unexpected bioavailability and are useful in methods of treating mammals.

More specifically, in accordance with this invention, there are provided particles consisting essentially of a crystalline drug substance having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 400 nm.

column 2, lines 38-43

The invention can be practiced with a wide variety of drug substances. The drug substance preferably is present in an essentially pure form. The drug substance must be poorly soluble and dispersible in at least one liquid medium. By "poorly soluble" it is meant that the drug substance has a solubility in the liquid dispersion medium of less than about 10 mg/ml, and preferably of less than about 1 mg/ml. A preferred liquid dispersion me-

col. 3, lines 38-45

Representative illustrative species of drug substances useful in the practice of this invention include:

17-α-pregno-2,4-dien-20-yno-[2,3-d]-isoxazol-17-ol (Danazol);

5α,17α,-1'-(methylsulfonyl)-1'H-pregn-20-yno[3,2-c]-pyrazol-17-ol (Steroid A);

col. 4, lines 15-20

EXAMPLE 2

PVP Modified Danazol Particles Prepared in a Ball Mill at Low Solids.

A nanoparticulate dispersion of Danazol was prepared using a ball mill process. A 600 ml cylindrical glass vessel (inside diameter=3.0 inches (7.6 cm)) was filled approximately halfway with the following grinding media:

Grinding media: zirconium oxide grinding spheres (made by Zircoa, Inc.)
Media size: 0.85–1.18 mm diameter
Media volume: 300 ml

The following dry ingredients were added directly to this glass vessel:

Danazol (micronized): 10.8 g
Polyvinylpyrrolidone K-15: 3.24 g
High purity water: 201.96 g

Danazol was purchased in the micronized form (average particle size 10 microns) from Sterling Drug Inc. and the polyvinylpyrrolidone was K-15 grade produced by GAF. The cylindrical vessel was rotated horizontally about its axis at 57% of the "critical speed". The critical speed is defined as the rotational speed of the grinding vessel when centrifuging of the grinding media occurs. At this speed the centrifugal force acting on the grinding spheres presses and holds them firmly against the inner wall of the vessel. Conditions that lead to unwanted centrifuging can be computed from simple physical principles.

After 5 days of ball milling, the slurry was separated from the grinding media through a screen and evaluated for particle size with the sedimentation field flow fractionator. The number average particle diameter measured was 84.9 nm and the weight average particle diameter was 169.1 nm. The particles varied in size from 26 to 340 nm. The amount and type of surface modifier was sufficient to provide colloidal stability to agglomeration and to maintain a homogeneous blend of ingredients assuring precise material delivery during subsequent processing steps.

(c) Claims 35, 36, 49, 63, and 64 are rejected under 35 U.S.C. § 103(a) over Edwards et al. U.S. Patent No. 5,985,309 in view of Dalby et al. U.S. Patent No. 5,202,110 ("Dalby").

The '309 reference is relied upon for all that it teaches as stated above in part (a) of this section.

Dalby, '110, is relied upon for the teaching of "non-CFC" propellant (e.g. formulations tabulated in Figure 5A; col. 2, lines 20-26; title, claims 1, 11, 18).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of '309 and '110 to provide propellant driven metered dose inhalers wherein the propellant is a "non-CFC" propellant, thereby

providing "environmentally friendly" propellant compositions of the '309 compositions that provided distribution to the deep tissues of the lungs.

Below are relevant citations from the Dalby reference (USPN 5,202,110):

1. An aerosol formulation for use in a metered dose inhaler, comprising:
a pharmaceutically acceptable inhalable propellant; and
a clathrate or molecular association of beclomethasone diproprionate employed as inhalable medicant dissolved or dispersed in said propellant, said clathrate or molecular association of beclomethasone diproprionate being formed with a compound selected from the group consisting of 1,1-dichloro-2,2,2-trifluoroethane, 1,1-dichloro-1-fluoroethane,

and dimethyl ether, said clathrate or molecular association being of a particle size which permits inhalation.

11. An aerosol formulation for use in a metered dose inhaler, comprising:

beclomethasone diproprionate at a concentration of 50 μg/63 μl or less; and
a propellant blend including 1,1-dichloro-2,2,2-trifluoroethane and a propellant selected from the group consisting of dimethyl ether, propane, and 1,1,1,2-tetrafluoroethane, said beclomethasone diproprionate being completely dissolved in said propellant blend.

claim 11 continued

18. The aerosol formulation of claim 1 wherein said pharmaceutically acceptable inhalable propellent is selected from the group consisting of trichlorofluoromethane, dichlorofluoromethane, 1,2-dichloro-1,1,2,2-tetrafluoroethane, 1,1-dichloro-1-fluoroethane, 1,1-dichloro-2,2,2-trifluoroethane, 1,1,1,2-tetrafluoroethane, n-butane, isobutane, propane, perfluoropentane, and dimethyl ether.

and (d) Claims 120 & 121 are rejected under 35 U.S.C. § 103(a) over Edwards et al. U.S. Patent No. 5,985,309 in view of Goodman & Gilman's, "The Pharmacological Basis of Therapeutics, Ninth edition, McGraw-Hill, 1996, page 666 ("Goodman").

Edwards et al (5,985,309, hereafter '309) is relied upon for all that it teaches as stated above, including the aerosol administration of steroids.

Goodman teaches that beclomethasone dipropionate is a known steroid administered for the treatment of asthma in aerosol formulations (pg. 666).

Accordingly, it would have been obvious to one skilled in the art at the time of the to administer beclomethasone dipropionate in the formulation of '309 with the motivation of providing a composition for the treatment asthma or asthma invention.

Below are relevant citations from the Goodman:

> Systemic glucocorticoid administration long has been employed to treat severe chronic asthma or severe acute exacerbations of asthma (McFadden, 1993; Greenberger, 1992). The development of aerosol formulations significantly improved the safety of glucocorticoid treatment, allowing it to be used for moderate asthma (Lipworth, 1993; Pavord and Knox, 1993; Busse, 1993). Asthmatic subjects who require inhaled β_2-adrenergic agonists four or more times weekly are viewed as candidates for inhaled glucocorticoids (Anonymous, 1991; Israel and Drazen, 1994; Barnes, 1995). In the United States, *beclomethasone dipropionate*, *triamcinolone acetonide*, and *flunisolide* are available as metered dose inhalers. Nebulizer solutions are not available. *Budesonide dipropionate* and *fluticasone propionate* are available in Europe and elsewhere for use in asthma and were approved by the United States Food and Drug Administration in 1994 for management of seasonal and perennial allergic rhinitis under the trade names RHINOCORT and FLUTICASONE, respectively. There are no convincing data that any of the drugs cur-
>
> **Goodman, pg. 666, left column**

> ***Inhaled Glucocorticoids.*** The dose of inhaled steroids must be empirically determined for each patient and should be based on amount of drug rather than the number of inhalations, given the six-fold variation in the micrograms delivered per inhaler activation for the available preparations. In mild to moderate asthma, as little as 300 to 400 μg/day can be effective. In severe asthma, total doses up to 2000 μg/day have been recommended, although it is possible that no further benefits accrue beyond 1600 μg/day (Lipworth, 1993). High doses of inhaled glucocorticoids are impractical with the low-dose beclomethasone preparations available in the United States; triamcinolone or flunisolide should be used instead when high doses are required. Beclomethasone and triamcinolone initially are given 3 to 4 times daily; flunisolide is used twice daily. If symptoms are controlled adequately, the same total number of inhalations can be tried using a twice daily regimen for all of the preparations. Patients may achieve better results dosing three or four times daily rather than twice daily. With high-dose inhaled glucocorticoids, use of a spacer device will reduce the risk of adverse effects (*see* below) and should be considered mandatory.
>
> **Goodman, page 666, left column**

Asthmatic patients maintained on inhaled glucocorticoids s
improvement in symptoms and lowered requirements for "res
with β-adrenergic agonists (Laitinen *et al.*, 1992; Haahtela *et*
1991; Haahtela *et al.*, 1994). Beneficial effects may be seen wi
1 week of starting inhaled glucocorticoids. Improvement, in term
reduced bronchial hyperreactivity, may continue for several mo
(Juniper *et al.*, 1990). When directly compared to regular use o
haled β-adrenergic agonists, inhaled glucocorticoids provide b
symptom control (Laitinen *et al.*, 1992; Haahtela *et al.*, 1991). A
cent study showed that, during treatment with inhaled budeso
(600 μg twice daily) for 2 years, bronchial hyperreactivity rema
improved throughout the study (Haahtela *et al.*, 1994). After 2 y
most patients were able to reduce their dose of budesonide to
μg twice daily without loss of control of their asthma. Upon c
plete discontinuation of budesonide, bronchial hyperreactivity
turned, and symptoms usually worsened, although one-third of
tients were able to completely discontinue their budesonide inh
without symptomatic worsening after prolonged treatment. Base
these findings, periodic attempts to discontinue inhaled glucocortic
should be considered in patients who are extremely well controll

Goodman, page 666, right column

(10) Response to Argument

(a) The Appellant argues that Edwards does not teach or suggest spherical, dry powder composition of nanosized drug particles, contending that Edwards only teaches rough and amorphous non-spherical drug particles. Contrary to Appellant's assertions, it is the Examiner's position that the prior art as known and expressed in Edwards teaches smooth and spherical microparticle drug for inhalation (col. 9, lines 11-21). Appellant argues that the claimed dry powder aerosol comprising aggregates of spherical drug particles is a significant advance over the non-spherical single particles of drug because according to Appellant, the spherical shape of particles positively influences aggregation of the drug particles and that this is crucial for the initial impact of the drug particles in the upper respiratory tract and subsequent retention in the lung. It is the Examiner's position that delivery of the drug is a matter of choice and design, and that whether in the form of aggregates or single particles, the key issue is delivering the drug in a form that can reach the alveoli of the lung. It is also noted that both the polymers comprising the

micron-sized particles taught by Edwards and the therapeutic agents contained therein are obviously nanosized particles, because the size of molecules are on the nanometer length scale. Furthermore, given that the particles taught by Edwards are micron-sized, these are obviously aggregates of nanometer particles (i.e. molecules), because it is only through the association (i.e. aggregation) of nanometer-sized molecules via intermolecular interactions that micron-sized particles could result.

Appellant asserts that the aerodynamic behavior of non-spherical drug particles would present poor airflow to upper airways of the respiratory tract. The Examiner disagrees with Appellant's position, as Appellant provides no evidence establishing support for this assertion. Moreover, Edwards teaches that the nanosized drug particles in aerosol formulation can be effectively delivered to the alveoli of the lung' (abstract; col. 5, line 35 and col. 10, line 35-45). Appellant contends that the nanoparticle drug aggregates in a liquid medium must be able to redisperse in order to establish contact with and be absorbed by the nasal and pulmonary tissues arguing that there is no teaching or suggestion in Edwards that the drug particles redisperse upon contact with liquid medium. Examiner posits that Appellant claims nanoparticles of drug and not a liquid dispersion medium. In this regard, it is noted that Appellant indicates no specific liquid medium for dispersion of drug particles. Furthermore, Examiner disagrees with Appellant's position because the disclosures in Edwards teach that the drug particles may be fabricated with appropriate material, surface roughness, diameter and tap density for localized delivery to selected regions of the respiratory tract (col. 10, line 45-55) including delivery to the alveoli (col. 10, line 35 and col. 28, line 35-40). The Appellant also alleges that Edwards does not teach crystalline nanoparticulate particles. The Examiner respectfully disagrees. Edwards

teaches several different therapeutic agents, including salmeterol (col. 12, line 41), which is a small molecule therapeutic, available in crystalline form. The selection of a crystalline therapeutic agent is obviously something that would have been apparent to a person of ordinary skill in the art, especially given that "recrystallization" is a commonly used purification technique of small molecule therapeutics. It is also the Examiner's position that Edwards disclosed that nanosized drug particles in aerosol form were delivered to the alveoli of the lung (col. 3, line 330-35 and col. 5, line 30-40).

(b) Appellant argues that Liversidge does not disclose aerosol formulation of nanoparticle drugs, contending that the teaching in Edwards discloses significant difficulties with respect to aerosol preparation and delivery. The Examiner disagrees with Appellant's position because the disclosure in Edwards teaches:

> (1) Incorporation of surfactants into the drug particles thereby effectively reducing the tendency of the particles to agglomerate (col. 7, lines 20-45) and
>
> (2) The effective delivery of the drug particles in the lung col. 9, lines 40-60 and col. 10, lines 35-45).

While the disclosures in Liversidge hint of some level of agglutination of drug particles (col. 4, lines 60-65), it is the Examiner's position that overall, the disclosures in Liversidge are: (a) in the same field of endeavor as that in Edwards' nanosized drug particles that are surface modified in liquid dispersion (col. 3, line 45) and (b) address similar problems that were raised in Edwards concerning nanosized drug delivery formulations through the respiratory tract and therefore inhalation (col. 5, line 1 and col. 12, line 50). It is noted that both Liversidge and Edwards are

indeed in the same field of endeavor, because both references teach pharmaceutical compositions, which may be administered to a subject's respiratory system (col. 8, lines 11-12 of Liversidge (i.e." oral" administration) and (e.g. Edward's abstract). Oral administration encompasses oral inhalation, and therefore administration to the respiratory system. It would have been apparent to an ordinary skilled artisan that the two possible routes of delivery of therapeutics to the pulmonary (i.e. respiratory) system are through the nose and the mouth. Delivery through the mouth is termed "oral" and delivery via the nose is termed "nasal."

(c) Appellant contends that neither Edwards nor Dalby (either singly, or in combination) teach or suggest aerosol composition of nanosized drug particles. Examiner disagrees with Appellant's position in that the teaching in Edwards regarding spherical, nanosized aerosol particles of drug was discussed above (col. 4, line 40-45 and col. 9, line 65). Dalby was relied on as teaching the propellant or aerosolized formulation for delivery of nanosized beclomethasone particles, albeit no chlorofluorocarbon was used (col. 7, line 10, continuing to col. 8, line 25).

(d) In traversing the rejection of claims 120 and 121 as unpatentable over Edwards in view of the secondary reference, Goodman and Gilman ("The Pharmacological Basis of Therapeutics. Ninth edition," McGraw-Hill, 1996, page 666) Appellant argues that while Edwards does not teach or suggest the claimed aerosol composition, that Goodman also fails to address the issue regarding benefits for delivering drugs nanoparticles in aggregate formulation. The Examiner disagrees with Appellant's position in light of the discussion respecting the teachings in Edwards and

further notes that Goodman teaches aerosolized formulation of glucocorticoids for delivery by inhalation (see page 666, first and second paragraphs).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) BPAI Order of September 18, 2006

Review of the prosecution history by the Board of Patent Appeals & Interferences (BPAI) found that the record was unclear as to whether the reference listed on the IDS submitted on June 24, 2003 (i.e. U.S. Patent No. 6,001,336) and the Soviet Union abstract 628930 listed on the IDS submitted on September 27, 1999 were considered. Soviet Union Abstract 628930 (i.e. SU 628930) was not found in the electronic file, and therefore the instant Examiner has concluded that it was not originally provided. The Examiner has obtained an English language abstract of SU 628930 from the Derwent database (copy provided herewith) and has considered this reference. A courtesy copy of the English Language abstract of SU 628930 has been mailed to the Appellant along with a PTO-90 communication addressing the issues raised by the order from the BPAI. U.S. Patent No. 6,001,336 has been considered. It is the Examiner's position that neither reference (i.e. U.S. Patent No. 6,001,336 or the English abstract of SU628930) merited reopening prosecution.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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